



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/774,178

02/01/2001

Tetsuya Ishizuka

P66351US0

7485

136 7590 12/20/2006
JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

WILDER, CYNTHIA B

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

12/20/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|---|---|--|--|
| Advisory Action Before the Filing of an Appeal Brief | Application No. 09/774,178 | Applicant(s) ISHIZUKA ET AL. | |
| | Examiner Cynthia B. Wilder, Ph.D. | Art Unit 1637 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 11 and 19.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment to advisory action.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit: 1637

Attachment to advisory Action

1. Applicant's amendment filed on 11/20/2006 is acknowledged and has been entered. Claims 11 and 19 are pending. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below.

Applicant's Traversal

2. Applicant traverses the rejection on the following ground: Applicant states that Nakahara and Kievits disclose optimal ITP concentrations for RNA amplification at 2.0 mM and 2.5 mM respectively. As such, since "a person of ordinary skill, upon reading the reference,...would be led" to use an optimal maximum ITP concentration of 2.5 mM, which is a direction divergent from the path that was taken by the applicant, i.e., using a minimum ITP concentration of 3.2 mM, the reference teaches away from the presently claimed invention, *Gurley*, 31 USPQ2d 1131.

Applicant states that the Examiner in the final rejection disputes this argument and states that "Nakahara does not teach an optimal concentration of ITP at 2.0 mM, but rather teaches the use of ITP at a concentration of 0-4mM which falls within the range claimed by Applicant".

Applicant states that the statement of rejection is clearly erroneous as to the alleged facts. Applicant states that Nakahara teaches *verbatim* that "the optimal ITP concentration was determined to be 2mM and further in the following experiments, NASBA was carried out in the presence of 2mM ITP". Applicant states that irregardless of what else Nakahara teaches, it cannot change the fact that the reference would have taught one skilled in the art that 2mM is the "optimal ITP concentration". Accordingly, Applicant maintains that a person of ordinary skill in the art upon reading the reference would be lead in a direction divergent from the path

Art Unit: 1637

that was taken by the applicant to use 2mM of ITP instead of using the minimum ITP concentration of 3.2 mM, in accordance with applicant's invention as presently claimed which render the claimed invention patentable over the cited reference. Applicant requests withdrawal of the instant rejections.

Examiner's Response

3. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: The examiner acknowledges Applicant's arguments, but maintains the claims 11 and 19 are unpatentable over Nakahara and Kievits. In response to Applicant's arguments that Nakahara and Kievits teaches an optimum concentration of 2mM and therefore teaches away from the instant invention of using ITP at 3.2 to 4.4 mM, MPEP 2144.05 states that "[I]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)." MPEP further states that "[S]imilarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)."

In this case, Nakahara provides a dose curve wherein ITP concentrations of 0-4 mM were utilized and a concentration of 3 to 4mM effectively provided an increase in fluorescent intensity over a control concentration (see Figure 1, page 1855). Similarly, Applicant's specification at pages 7, 8, 20, 21 and Figures 1-5 discloses dose curves utilizing ITP concentrations from 0-5 mM and is not limiting in the manner Applicant argues.

Art Unit: 1637

Additionally, MPEP 2144.05 states that "[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, Applicant's specification teaches a method of amplifying a target RNA using varying concentration of ITP from 0 to 5 mM (see pages 7, 8, 20, 21 and Figures 1-5). The cited prior art of Nakahara provides a similar teaching in the disclosure of a method of amplifying a target RNA using varying concentration of ITP from 0 to 4 mM. There is nothing in Applicant's claims or in the instant specification that teaches or suggests that a minimum concentration of 3.2 to 4.4 mM of ITP is *critical* to the instant invention. In fact, it appears that Applicant's invention attempts to determine optimum concentrations of ITP through routine experimentation. As noted earlier, MPEP states "it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In regards to Applicant's arguments that the reference teaches away from the instant invention by the teaching of an optimum concentration, MPEP 2123 states that "[D]isclosed examples and *preferred embodiments do not constitute a teaching away* from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)". In this case, the Examiner agrees that Nakahara teaches an optimum concentration of 2 mM. However, this does not change the fact that Nakahara effectively provides teaching of the amplification of RNA at concentration of ITP from 0.5 to 4 mM (see Figure 1), which

Art Unit: 1637

encompasses concentrations claimed by Applicant. Hence according to MPEP, the teaching of Nakahara does not teach away from the instant invention, but rather provides a *prima facie* case of obviousness to one of ordinary skill in the art.

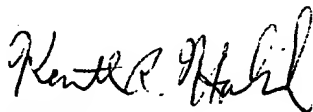
Applicant's arguments are not sufficient to overcome the prior art rejections under 35 USC 103(a). Accordingly, the rejections are maintained.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cbw


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

12/13/06